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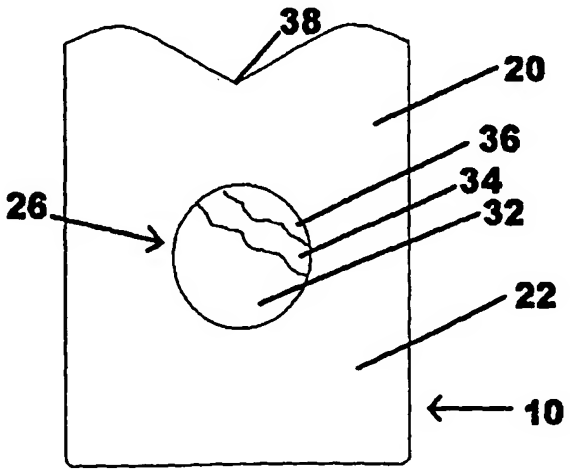
(54) Title: DISPOSABLE SELF-ADHESIVE FOOT PATCH



(57) Abstract: A disposable self-adhesive foot patch that is adhesively applied tot he foot for anatomical support to prevent and reduce fatigue and discomfort in the feet, legs, and lower limbs. The patch has increased breathability of the disposable self-adhesive patch while attached to the foot.

WO 02/43518 A2

DISPOSABLE SELF-ADHESIVE FOOT PATCH

FIELD OF THE INVENTION

The present invention relates to a disposable self-adhesive foot patch for application to the foot and lower ankle area. Specifically, the present invention relates to a disposable self-adhesive foot patch that provides anatomical support to the foot and lower ankle area to prevent and reduce fatigue and discomfort in the feet and legs.

BACKGROUND OF THE INVENTION

During each footfall in walking, forces are acting between the ground and the foot. These forces are usually referred to as ground reaction forces (GRF). They can be quantified using appropriate measuring devices. The order of magnitude of GRF for walking is 1 to 1.5 times a person's body weight. Studies have shown that there are typically two distinct phases of force when there is foot-ground interaction. First is when the foot collides with the ground and second is when the foot pushes off from the ground. The two phases of force have different consequences with respect to the human musculoskeletal system.

When the foot collides with the ground, the heel of the foot, for about 80% of individuals, strikes the ground first. This impact is generally short in nature and the body can not react and adjust to the sudden increase in force. Studies have associated this type of impact force with chronic and degenerative injuries such as plantar fasciitis and heel spurs. To assist the body in adjusting to the impact forces products that deform easily under load and dissipate energy decrease the impact force on the rearfoot area and help decrease injuries to the foot.

After the impact of the heel striking the ground, a normal human gait continues on to a second phase of force that occurs when the foot pushes off from the ground. The second phase effects the medial longitudinal arch of the foot. Pronation consists several motions including moving or drawing away from the axis of the leg, turning outward or inside out of the arch, and then flexing toward the back of the foot. Pronation is always accompanied by the movement of the heel and internal rotation of the leg and hip. While this process is a normal part of a human gait, excessive pronation is the source of many lower extremity pathologies, including muscle fatigue and inflammation, foot and knee joint pain, tendinitis, ligament strain, and even neurological damage. Excessive pronation also renders the gait less efficient since time and effort is wasted in collapsing (pronating) and recovering (surpination).

Foot devices have covered a broad range of materials and structures to help distribute the forces acting on the foot during a normal gait cycle. Such devices can be a padded flat surface or shaped to conform to the foot. When conformed to the foot, devices can be custom made to conform to a particular foot or devices can be made to fit to an average foot.

Custom shaped foot devices tend to be made from durable, rigid material that is designed to be worn every day. These devices tend to be expensive and require modification subsequent to fitting. Additionally custom devices are typically bulky and require replacement when the size of the foot changes. An example of such a device is shown in U.S. Pat. No. 4,360,027.

Other foot devices have been made from materials that deform under pressure. Such devices are exemplified by U.S. Pat. No. 6,138,383. These foot devices are designed for extended use in a person's footwear. These devices take the shape of a shoe insert covering either the entire bottom of the foot or some smaller area thereof.

Typically shoe inserts have difficulties in maintaining a cushioning and structural support for extended periods of time. The inserts can be bulky and make shoes uncomfortable to the foot. The inserts are subject to unsanitary conditions inside of the shoe environment including bacteria, dirt, sweat and odors. Also, these inserts cannot be used with all types of footwear, especially footwear that does not have an entirely enclosed construction such as sandals and some women's shoes. However, even devices that can be worn in sandals

or other open shoe structures still pose problems with the sweat produced by the foot.

The average human foot produces between 200 mL to 500 mL of moisture a day. Thus, the humidity within a shoe can be quite high. If an item is adhesively placed on the skin, the skin becomes wet and overhydration can occur. This effects the skin of the wearer and the adhesive properties of the item placed onto the skin of the foot. The addition of the frictional forces produced by walking, a product adhesively applied to the foot will have a tendency to peel off or migrate during movement.

Skin occlusion can negatively impact comfort and cause negative changes to skin structure. Skin overhydration can be a common problem in products that are attached to the skin. This can increase the chance of skin irritation and skin softening (maceration). As a result of maceration, the skin is more subject to abrasion due to normal movement, and skin disorders such as erythema (i.e. redness), heat rash, abrasion, pressure marks and skin barrier loss.

Such problems have been addressed with medical dressings. Patches or pads that attach directly to the skin are well known in the medical industry for wound dressings. While these types of bandages address the breathability issues (i.e. vapor permeability), they lack the anatomical structural support necessary for an foot device.

Another property of medical wound dressings is liquid absorption. Often medical wound dressings are designed to absorb fluids that emanate from the wound. Similarly, in the foot area, sweat glands produce enough fluid to result in maceration of the skin. A disposable article that can absorb some of the sweat produced by the foot is desirable. However, medical wound dressings are designed to absorb and hold bodily fluids. This type of design is undesirable for foot devices since the area available in a wearer's shoe is limited and an increase in volume of the foot device can cause discomfort. Therefore it is desirable to have an absorption layer included in the disposable self-adhesive foot patch acts more for wicking purposes and that allows for the incremental release of sweat after it is absorbed.

Patches or pads that attach directly to the foot and have provided foot support devices. Exemplary are JP Pat. No. 98868A (Kokai), JP Pat. No. 11-255635A (Kokai), and U.S. Pat. No. 6,120,473. These references fail to address the important problem of foot wetness. These references teach arch supporting

devices where adhesive is continuously coated onto the device that results in little or no vapor permeability of the device. As such, these devices can lead to foot discomfort if worn for an extended period of time. These devices do not provide a wicking element to remove the sweat from the foot to be transported away from the skin of the foot which can also alleviate overhydration problems.

Additionally, the device shown in U.S. Pat. No. 5,539,020 is prone to accumulate dirt and other material when in use because of its tackiness properties and can also result in excessive costs for disposable patches.

Accordingly, the need exists for a disposable device that provides anatomical structural support for the foot and lower ankle area that can be applied directly or indirectly to the skin and that is breathable to allow vapor permeability and liquid permeability.

SUMMARY OF THE INVENTION

The present invention relates to a disposable self-adhesive foot patch for application to the foot and lower ankle area comprising; a top flexible sheet having a first and second side wherein the top flexible sheet is substantially vapor permeable; a reinforcing layer, being substantially vapor permeable, having a first and second side; wherein the first side of the reinforcing layer is attached to the second side of the top flexible sheet; a bottom flexible sheet, being substantially vapor permeable, having a first and second side wherein the bottom flexible sheet is connected to the second side of the reinforcing layer and is connected to the second side of the top flexible sheet thereby making a pouch around the reinforcing layer; and an adhesive layer, being vapor permeable, applied intermittently to the second side of the top flexible sheet that attaches the disposable self-adhesive patch to the foot.

It has now been found that the present invention can provide anatomical support to the foot to prevent and reduce fatigue and discomfort in the foot and leg areas more effectively than traditional noncustomized foot devices. The present invention allows the wearer to position the foot device in a position to provide the greatest benefit to the wearer. The present invention also allows the wearer to select the properties they are most interested in using. e.g. whether the wearer wants heel support, toe support, ball area of the foot support, or any combination thereof.

The present invention is designed to be disposable to address the unsanitary conditions often found in permanent inserts. The present invention may be attached to the foot so as to not restrict the use of the present invention to closed shoe structures. The disposable self-adhesive foot patch can provide anatomical support with or without footwear. The ability of the disposable self-adhesive foot patch to deliver anatomical support is derived from the wearer being able to place an effective material to the desired portion of the foot. The wearer is able to place, for example, a longitudinal arch support in a position that is most effective to the wearer without having the disposable self-adhesive foot patch specifically fitted to the wearer's foot. The present invention is breathable to avoid the moisture problems associated with the foot area. The present invention may also be clear or skin-toned in appearance to address concerns over discreetness in wearing foot devices that are visible when the person has open footwear or no footwear. Additionally, the present invention may be light in weight to allow comfortable wearing in footwear and to reduce fatigue than can result from heavier foot devices.

These and other features, aspects, advantages, and variations of the present invention, and the embodiments described herein, will become evident to those skilled in the art from a reading of the present disclosure with the appended claims, and are covered within the scope of these claims.

BRIEF DESCRIPTION OF THE FIGURES

While the specification concludes with claims particularly pointing out and distinctly claiming the invention, it is believed that the invention will be better understood from the following description of the accompanying figures in which:

Fig. 1 is an exploded top view of a preferred embodiment of the disposable self-adhesive patch

Fig. 2 is a perspective view of a preferred embodiment of the disposable self-adhesive patch in Fig. 1; and

Fig. 3 shows the release paper being removed from the disposable self-adhesive patch in Fig. 1; and

Fig. 4 shows the preferred embodiment of Fig. 1 attached to the rearfoot area.

The figures herein are not necessarily drawn to scale.

DETAILED DESCRIPTION OF THE INVENTION

All percentages, ratios and proportions herein are by weight of the final composition, unless otherwise specified. All temperatures are in degrees Celsius (°C) unless otherwise specified. All documents cited are incorporated herein by reference in their entireties. Citation of any reference is not an admission regarding any determination as to its availability as prior art to the claimed invention.

The term "disposable" is used herein to describe articles which are not intended to be laundered or otherwise restored or reused as an article (i.e. they are intended to be discarded after a single use and, preferably, to be recycled, composted or otherwise disposed of in an environmentally compatible manner.)

As used herein, the term "layers" refers to identifiable components of the structure, and any structure referred to as a "layer" may actually comprise a laminate or combination of several types of materials as hereinafter described. As used herein, the term "layer" includes the terms "layers" and "layered." For purposes of this invention, it should be noted that the various materials, layers, and structures according to the present invention may or may not be generally planer in nature, and may be shaped or profiled in any desired configuration.

The term "flexible" refers to materials which are compliant and will readily conform to the general shape and contours of the human body.

The term "anatomical support" refers to skeletal and/or muscular support received from the present invention including, but not limited to cushioning, shock absorption, and bracing properties.

The term "connecting means" refers to any type of adhesive bonds, pressure bonds, mechanical bonds, and the like.

THE DISPOSABLE SELF-ADHESIVE FOOT PATCH

The disposable self-adhesive patch shown in Fig. 1 comprises a top flexible sheet (20), an adhesive layer (22), release paper (24), reinforcing layer (26) comprising a deformable foam (34) and a stiff foam (36), and a bottom flexible sheet (32).

Top flexible sheet (20) is formed in an rectangular shape with one notched edge (38), with top flexible sheet first side (21) facing downwards. Top flexible sheet second side (23), facing upwards, is intermittently coated with an adhesive layer (22) and a release paper (24). Edge of release paper (24) is colored so as

to indicate an edge that wearer can grasp to remove release paper (24). Reinforcing layer (26) comprising a deformable foam (34) and a stiff foam (36), is attached to top flexible sheet second side (23) on reinforcing layer first side (27). Stiff foam (36) is attached to top flexible sheet second side (23). Deformable foam (34) is attached to stiff foam (36). Bottom flexible sheet (32) forms a pouch around reinforcing layer (26) on bottom flexible sheet second side (33) and then is adhesively attached to top flexible sheet second side (23). Top flexible sheet (20) and bottom flexible sheet (32) can be any breathable sheet as defined by the description below. Bottom flexible sheet (32) is preferably a soft, absorbent material. Reinforcing layer (26) preferably contains more than one material. the preferred deformable foam (34) can be any open celled or closed cell foam material. The preferred stiff foam (36) can be any open celled or closed cell foam material that exhibits less flexibility than deformable foam (34).

Release paper (24) is removed from disposable self-adhesive patch (10) when wearer wishes to utilize disposable self-adhesive patch (24) as shown in FIG. 3. Disposable self-adhesive patch (10) is then placed onto the foot on the heel area by the wearer as shown in FIG. 4.

Example of the invention is set forth hereinafter by way of illustration and is not intended to be in any way limiting of the invention.

FLEXIBLE SHEET

There are two different flexible sheets described in the present invention. The top flexible sheet and the bottom flexible sheet may or may not be the same material in the present invention.

Numerous attempts have been disclosed that are directed to improving wearer skin condition by reducing the risk of creating overhydrated skin or by allowing already overhydrated skin to dehydrate to a level closer to unoccluded skin.

More or less breathable devices or materials are described in U.S. Pat. Nos. 4,627,847, 4,648,876, 4,578,069, 4,713,068, 4,758,339, 4,833,172, 4,923,650, 5,254,111, 5,492,751, 5,599,420 and 5,628,737, in published European Patent applications EP 315,013 and EP 710,471, and in published PCT applications WO 95/16,562 and WO 95/16,746. Generally, all such devices or materials balance gas permeability and liquid impermeability. This becomes particularly apparent when considering materials having apertures or pores,

whereby an increase in pore size will allow easier gas permeation, but also easier liquid permeation. Other approaches are aimed at keeping only part of the article breathable, by a part being covered by non-breathable material, but having other parts of the article made of breathable materials.

The flexible sheet is preferably compliant, soft feeling, and non-irritating to the wearer's skin. Further, the flexible sheet may be liquid permeable, permitting liquids to readily penetrate through its thickness. A suitable flexible sheet may be manufactured from a wide range of materials such as woven and nonwoven materials (e.g., a nonwoven web of fibers); polymeric materials such as apertured formed thermoplastic films, apertured plastic films, and hydroformer thermoplastic films; porous foams; reticulated foams; reticulated thermoplastic films; and thermoplastic scrims. Suitable woven and nonwoven materials can comprise natural fibers (e.g., wood or cotton fibers), synthetic fibers (e.g., polymeric fibers such as polyester, polypropylene, or polyethylene fibers) or from a combination of natural and synthetic fibers. When the flexible sheet comprises a nonwoven web, the web may be manufactured by a wide number of known techniques. For example, the web may be spunbonded, carded, wet-laid, melt-blown, hydroapertured, hydroentangled, combinations of the above, or the like. Such nonwoven webs may be bonded using means known to the art, such as chemical bonding, latex bonding, thermal bonding, and the like.

The flexible sheet of the present invention may comprise a single layer or it may comprise more than one layer or material.

In one aspect of the present invention the breathable flexible sheet provides a skin care benefit (e. g. overhydration protection). While not being bound by theory, the following is believed to provide an explanation of how this cooperation provides such a benefit. Interfere with the normal transport of water vapor into and out of the skin leads to excessive relative humidity in the void space by the wearer's skin. By providing a means for transport of such excess moisture the driving force toward overhydration is reduced.

An essential element of the present invention is the use of materials which are sufficiently permeable to gases, such as air, water vapor, or other volatile materials. Apart from diffusion, gases or vapor can pass through a solid material by small capillary transport (slow), or convective transport (fast). Permeability can be assessed by the well known Mass Vapor Transmission Rate (MVTR), expressed in units of g/24 h/m^2 under various driving forces. For purposes of the

present invention, the method, as is described in the TEST METHODS section below, involves calcium chloride which adsorbs moisture passing through the test specimen that is exposed to an environmental relative humidity of 75% at 40°C. An alternative method of assessing gas permeability uses an air permeability test (also described in the TEST METHODS section below), whereby air is sucked through a test specimen under defined conditions such as a specific pressure drop across the sample. As the air permeability test relates to high penetration rates, it is more applicable to materials allowing convective flow (fast) rather than the diffusional or capillary transport dominated (slow) materials.

A suitable material for use as a breathable flexible sheet for purposes of the present invention has a MVTR value of at least about 200 g/24 h/m^2. Preferably, the MVTR of breathable flexible sheets of the present invention is at least about 400 g/24 h/m^2. More preferably, the MVTR of the breathable flexible sheet is also least 500 g/24 h/m^2. Examples of such materials suitable for use in the present invention include woven and nonwoven fiber materials, apertured polymeric films, porous foams, reticulated foams, reticulated polymeric films, and polymeric scrims.

With respect to the present invention, materials manufactured or treated to be permeable can be classified as follows:

Table 1

MVTR	Permeability Range (g/m^2 /24 h)
non-permeable	up to about 200
low permeability	about 200-500
medium permeability	about 500-1000
high permeability	about 1000-2000
very high permeability	more than about 2000

As noted above, materials with low breathability, that is materials with MVTR values greater than about 200-500 g/24 h/m^2 are effective in allowing transport of moisture vapor from the void space between a wearer's body and the present invention.

Flexible sheets can comprise nonwoven materials, which have been made liquid impermeable such as by either minimizing the non-woven pore size e.g. by

combining spunbonded webs with meltblown layers (SMS) or by other treatments. The flexible sheet may have two or more zones, at least a first zone having a mass MVTR value of at least about 200 g/24 h/m^2 and one or more of the remaining zones has a MVTR value greater than said MVTR value of the first zone.

The flexible sheet may be made using a hydrophilic substrate to promote rapid transfer of sweat through the flexible sheet. If the material is hydrophobic, at least the upper surface of the flexible sheet is treated to be hydrophilic so that liquids will transfer therethrough more rapidly. This diminishes the likelihood that fluids will flow off the flexible sheet rather than being drawn through the flexible sheet. The flexible sheet can be rendered hydrophilic by treating it with a surfactant. Suitable methods for treating the flexible sheet with a surfactant include spraying the flexible sheet with the surfactant and immersing the material into the surfactant. A more detailed discussion of such a treatment and hydrophilicity is contained in U.S. Pat. No. 4,988,344 and U.S. Pat. No. 4,988,345.

REINFORCING LAYER

The reinforcing layer preferably is non-irritating to the wearer's skin and provides the desired properties necessary to provide anatomical support to the wearer. Desired properties is depended upon the function and use of the reinforcing layer. The reinforcing layer of the present invention may comprise a single material or it may comprise more than one material as shown in FIG. 2 with a deformable foam (34) and a stiff foam (36). Exemplary materials include natural and man-man materials such as polymeric foams, gels, laminates, resins, rubbers, or other viscoelastic materials.

There are no purely elastic or purely viscous materials in nature; there is always a combination of these two properties. All materials comprise elastic and viscous properties and are referred to as viscoelastic. A material is considered "elastic" if it is predominantly elastic, i.e. if it has only to a small extent viscous properties. On the other hand, a material is "viscous", if it has predominately viscous properties, i.e. only to a small extent elastic properties. Elastic materials store energy, i.e. convert mechanical work into potential energy, which is recoverable. Viscous materials do not store energy, but when stressed dissipate it as heat as they flow. This dissipation gives highly damped motion.

The reinforcing layer for a rearfoot area will preferably comprise viscous materials to help decrease and dissipate the striking force of the foot as in comes into contact with the ground. Alternatively, the reinforcing layer is preferably made of elastic materials for a forefoot area to help return energy to the push-off portion of the human gait.

Additional properties considered for the reinforcing layer include resistance to compression deflection, flexibility, recovery from compression deflection, integrity, softness, stiffness, vertical wicking, absorbency characteristics, absorbency under pressure and vapor permeability. The specific, somewhat interrelated mechanical properties which have been identified as contributing to the realization of polymertic foams especially suitable for use in anatomical structural support devices are as follows:

A) Resistance to Compression Deflection

An important mechanical feature of the reinforcing layer of this invention is the strength of the reinforcing layer as determined by its resistance to compression deflection or shock absorption. Compression deflection is a measure of the ability of a material to handle immediate forces placed upon it, and also the consistency with which a material handles each individual event.

B) Flexibility

The reinforcing layer of the present invention must be sufficiently flexible so that they can be utilized in anatomical structural support products that will conform to the body shape of the wearer. Characterization of reinforcing layer herein as flexible, therefore, means that these reinforcing layers can be deformed or bent to the extent necessary for use in present invention without significant damage to its structural integrity or significant loss to other properties.

C) Recovery From Compression Deflection

Recovery from compression deflection relates to the tendency or propensity of a piece of material to return to its original dimensions after being deformed or compressed under forces encountered in manufacture, storage or use.

D) Reinforcing Layer Integrity

While not absolutely essential for the realization of operable or useful reinforcing layer materials, the materials of this invention will preferably possess the additional mechanical attributes of structural integrity in use. For example, materials that will be employed in this invention will be subjected to both dynamic

and static forces which arise when the wearer walks. Such forces may not only tend to compress the material, but such forces may also tend to rip or tear or otherwise fragment the material structure. Obviously, it would be advantageous for material structures which are to be used in this manner to have sufficient structural integrity to minimize the incidence of material tearing or fragmenting in use.

E) Softness

The reinforcing layer materials of this invention may also be configurations wherein the material surface may come in close proximity to or even in actual contact with the wearer's skin. Accordingly, it would be very desirable for the surface of the reinforcing layer herein to be acceptably soft and non-irritating to the touch.

F) Stiffness

The reinforcing layer materials of the present invention may also be intended to give some structural support in addition to cushioning. Accordingly, it may be desirable for the reinforcing layer to include materials that have a diminished flexible property.

G) Vertical Wicking Performance

Vertical wicking performance is the ability of the reinforcing layer to transfer body liquids away from the surface of the skin into the reinforcing layer.

H) Absorbent Capacity and Absorbent Capacity Under Pressure

Absorbent capacity is the total amount of test fluid which a given reinforcing layer sample will absorb into its structure per unit mass of solid material in the sample. Absorbent capacity under pressure refers to the amount of that fluid held under no confining pressure (free capacity) which the reinforcing layer will retain within its structure when the sample is subjected to compressive force.

I) Vapor Permeability

The reinforcing layer should have a MVTR at least 200 g/24 h/m^2, preferably at least 400 g/24 h/m^2, and most preferably at least 500 g/24 h/m^2 as described in TEST METHOD below.

If foam materials are used for the reinforcing layer, such foam material can have an relatively open celled or a relatively closed celled character. The type of character depends upon whether and/or the extent to which, the cell walls or boundaries, i.e. the cell windows, are filled or taken up with material. For

purposes of the present invention, a foam material in which 80% of its cells which have intercellular openings or "windows" which are large enough to permit ready fluid transfer from one cell to the other within the foam structure are relatively open-celled foam structures.

ADHESIVE LAYER

The disposable self-adhesive foot patch according to the present invention may be coated on the surface or impregnated into the flexible sheet applied to the foot with any suitable adhesive. A suitable adhesive is an adhesive which gives the requisite degree of adhesion and which in non-toxic and non-allergenic. The adhesive may or may not be vapor permeable.

Ideally, the degree of adhesion should be such that the disposable self-adhesive foot patch remains in place for the duration of the user's use. The disposable self-adhesive foot patch should be relatively easily removable at the end of the use.

The adhesive layer should allow for vapor permeability with a MVTR measurement at least 200 g/24 h/m^2, preferably at least 400 g/24 h/m^2, and most preferably at least 500 g/24 h/m^2 as described in TEST METHOD below. This can be accomplished by avoiding solid films of adhesive. Application of the adhesive layer can be by any type of intermittent coating such as spiral coating, dotting adhesive, stripes of adhesive or any other type of intermittent coating.

RELEASE PAPER

The disposable self-adhesive foot patch according to the present invention is preferably supplied with a suitable material such as paper over the adhesive layer, such that the material will stay on the disposable self-adhesive foot patch until removed by the user while allowing the adhesive to remain on the disposable self-adhesive foot patch. Patches may be packaged individually or, for suitably shaped patches, in a continuous package, e.g. a roll, individual patches being separated by lines of weakness such as perforations.

The release paper can be in the form of one sheet or multiple sheets. The first edge of the release paper that is to be removed first is preferably indicated with some visual means so that the user can easily see the edge of the release paper.

SWEAT ABSORPTION LAYER

The disposable self-adhesive foot patch according to the present invention may include a sweat absorption layer that temporally retains the sweat and then allows water vapor to permeate out of the disposable self-adhesive foot patch. A material that has moisture absorbency tendencies and air permeability from 30 to 50 g/m^2 25°C 90% relative humidity, more preferably 45 g/m^2 25°C 90% relative humidity as measured by the above described air permeability test.

The disposable self-adhesive foot patch according to the present invention should be light in weight. The disposable self-adhesive foot patch should be between 100 grams to 0.0001 grams, preferably between 50 grams and 0.0001 grams, and most preferably between 15 grams and 0.0001 grams.

TEST METHODS

Moisture Vapor Transmission Rate

The Moisture Vapor Transmission Rate (MVTR) determines the amount of moisture adsorbed by calcium chloride in a "up" like container that is covered by a test specimen where the moisture source is a controlled temperature/humidity environment (40°+-.3°C./75.+-.3% relative humidity) separated from the calcium chloride by the test specimen.

The sample holding a cup is a cylinder with an inner diameter of 30 mm and an inside height from bottom to top flange of 49 mm. A flange having a circular opening to match the opening of the cylinder can be fixed by screws, and a silicone rubber sealing ring with an opening matching the inner diameter of the cup, fits between the top flange and the cylinder. The test specimen is positioned such that it covers the cylinder opening. The specimen is tightly fixed between the silicone rubber sealing and the upper flange of the cylinder so it acts as a barrier to moisture transport.

The equipment as well as the test specimen should be equilibrated to the temperature of the controlled environment prior to testing.

The absorbent desiccant material is calcium chloride, such as can be purchased from Wako Pure Chemical Industries Ltd., Richmond, Va. under the product designation 030-00525. If kept in a sealed bottle, it can be used directly.

It also can be sieved to remove lumps, or excessive amounts of fines, if existing. It also can be dried at 200°C. for about 4 hours.

The calcium chloride is weighed (15.0.+-.0.02 g) into the cup, and tapped lightly so as to level it out, such that the surface is about 1 cm from the top of the cup.

A test sample is placed flat and overlapping with the seal over the opening, and the seal and the top flange are affixed by the screws without over tightening. The total weight of the cup assembly is accurately recorded to four decimal places, and the assembly is placed into the constant temperature/humidity chamber.

After 5 hours exposure to the test humidity (without opening of chamber), the sample is removed and immediately covered tightly with a non-vapor permeable plastic film such as SARAN WRAP. After cooling about 30 minutes to allow for temperature equilibration, the plastic film is removed and the assembly is reweighed.

The MVTR value is then calculated by determining the moisture increase over 5 hours due to transport through the circular opening and converting the result to units of "g/24 h/m^{2}".

For each test, three replicates should be run, the resulting values will be averaged, and the result rounded to the nearest 100 value.

Overall, this method is applicable to thin films, multi-layer laminates and the like. Experience has shown, that typical standard deviations range between 50 and 250 g/24 h/m^2 for averaged values of up to about 5000 g/24 h/m^2.

Air Permeability

The air permeability is determined by measuring the time in which a standard volume of air is drawn through the test specimen at a constant pressure and temperature. This test is particularly suited to materials having relatively high permeability to gases, such as nonwovens, apertured films and the like.

The test is operated in a temperature and humidity controlled environment, at 22°.+-.2°C. and 50.+-.2% relative humidity. The test specimen has to be conditioned for at least 2 hours.

Suitable test equipment is manufactured by Hoppe & Schneider GmbH, Heidelberg, Germany, under the designation "Textiluhr nach Kretschmar". The apparatus is essentially a bellows in a vertical arrangement, with its upper end being mounted in a fixed position, and the lower end being releasably held at its

upper position, which can be loosened by means of a release handle to slide under controlled conditions to the lower position, thereby increasing the volume inside the bellows by pulling air through the test specimen which covers the air inlet opening at the upper end of the bellows. The test specimen is firmly held to cover the air inlet opening by means of a fastening ring having an area of either 5 cm^2 or 10 cm^2 (allows for different samples sizes and/or different permeability ranges). If the 10 cm^2 ring is used, the sample should be at least 55 mm wide, for the 5 cm^2 ring a sample width of at least 35 mm is required. For both, the samples should have a length of about 150 mm.

Optionally, the sample holding device can comprise a stretching element, such as to enable measurement of elastic materials under stretched conditions.

The equipment comprises a stopwatch (1/100 sec increments) which automatically measures the time between the operation of the release handle, which starts the sliding of the bellows, and the bottom of the bellows reaching its lower or stop position.

The air permeability of the material can then be calculated by dividing a constant (provided by the supplier for each individual test apparatus; K is about 200.000 for a tested area of 5 cm^2, and about 400.000 for an area of 10 cm^2) by the time as measured in seconds, resulting in units of: liters/cm^2 /sec.

The test is repeated once for each test sample, and should be repeated on 10 samples to provide a representative value for a material.

EXAMPLE 1

The embodiment depicted in Fig. 1 is intended for use as a heel patch. The top flexible sheet is brown body tape sold under the tradename KINESHIO TAPE or KINESIO TEX by Kineshio K.K. Japan. The adhesive layer is an acrylic synthetic-resin and is intermittently applied by 2 mm wide stripes with 1 mm space between stripes to the top and bottom flexible sheet. The release paper comprises two independent papers. The first paper covers approximately 75% of the first flexible sheet area. The second paper covers the remaining 25% of the first flexible sheet. The release paper edges on the interior of the disposable self-adhesive foot patch are dyed a bright orange color to indicate where the wearer is to begin peeling the release paper from the disposable self-adhesive patch. The bottom flexible sheet is a nonwoven cotton/polyethylene teraphalate

(PET) blend. The deformable foam is an open celled polyurethane foam. The stiffer foam is a closed cell foam material sold under the tradename LION SHEET. The entire weight of the disposable self-adhesive patch is 3.1 grams.

WHAT IS CLAIMED IS:

1. A disposable self-adhesive foot patch comprising:

(a) a top flexible sheet having a first and second side wherein the top flexible sheet is substantially vapor permeable;

(b) a reinforcing layer, being substantially vapor permeable, having a first and second side; wherein the first side of the reinforcing layer is attached to the second side of the top flexible sheet;

(c) a bottom flexible sheet, being substantially vapor permeable, having a first and second side; wherein the first side of the bottom flexible sheet is connected to the second side of the reinforcing layer and extends around the reinforcing layer to form a pouch by connecting to the second side of the top flexible sheet by connecting means;

(d) an adhesive layer, being substantially vapor permeable, wherein the adhesive is intermittently applied to the second side of the top flexible sheet whereby the adhesive layer adhesively attaches the disposable self-adhesive patch to the foot; and

wherein substantially vapor permeable means MVTR values are at least 200 g/24 h/ m^2.

2. The disposable self-adhesive foot patch of Claim 1 wherein the disposable self-adhesive foot patch is hydrophilic.

3. The disposable self-adhesive patch of Claim 1 wherein the reinforcing layer is one or more materials.

4. The disposable self-adhesive patch of Claim 3 wherein at least one material comprises a foam material.

5. The disposable self-adhesive foot patch of Claim 1 wherein the top flexible sheet is clear or skin-toned in appearance.

6. The disposable self-adhesive foot patch of Claim 1 wherein the bottom flexible sheet is clear or skin-toned in appearance.
7. The disposable self-adhesive foot patch of Claim 1 further comprising a liquid absorption layer.
8. The disposable self-adhesive foot patch of Claim 1 wherein the weight of the patch is less than 100 grams, preferably less than 50 grams, and most preferably less than 15 grams.
9. The disposable self-adhesive foot patch of Claim 1 further comprising a release paper substantially covering the adhesive layer.
10. The disposable self-adhesive foot patch of Claim 9 wherein the release paper has a visible means to indicate a removable edge of the release paper.
11. A disposable self-adhesive foot patch comprising:
    (a) a top flexible sheet having a first and second side that is clear or skin-toned in appearance wherein the top flexible sheet's MVTR values are at least 200 g/24 h/m^2;
    (b) a reinforcing layer with an MVTR value of at least 200 g/24 h/m^2 having a first and second side wherein the first side of the reinforcing layer is attached to the second side of the top flexible sheet and the reinforcing layer is comprised of one or more material;
    (c) a liquid absorption layer that is connected to the second side of the reinforcing layer by a connecting means;
    (d) a bottom flexible sheet with a MVTR value of at least 200 g/24 h/m^2, having a first and second side that is clear or skin-toned in appearance; wherein the bottom flexible sheet is connected to the liquid absorption layer and extends around the reinforcing layer to form

a pouch by connecting to the second side of the first flexible sheet by a connecting means;

(e) a adhesive layer having a MVTR value of at least 200 g/24 h/m^2, wherein the adhesive layer is intermittently applied to the top flexible sheet whereby the adhesive layer adhesively attaches the disposable self-adhesive patch to the foot;

(f) a release paper substantially covering the adhesive layer and having a visible means to indicate a removable edge of the release paper

whereby the disposable self-adhesive patch weight is less than 15 grams .

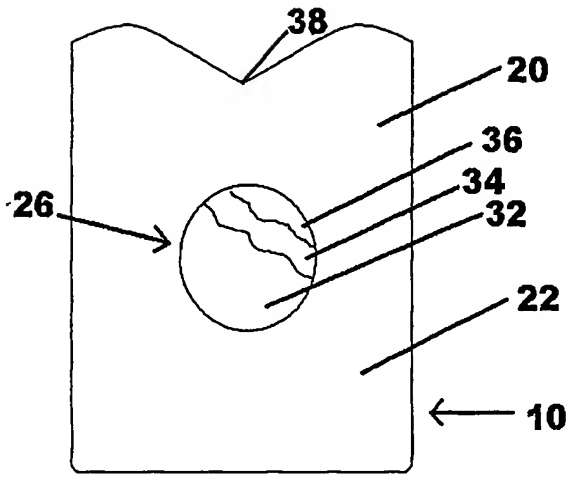


FIG. 1

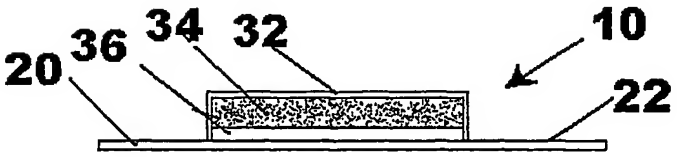


FIG. 2

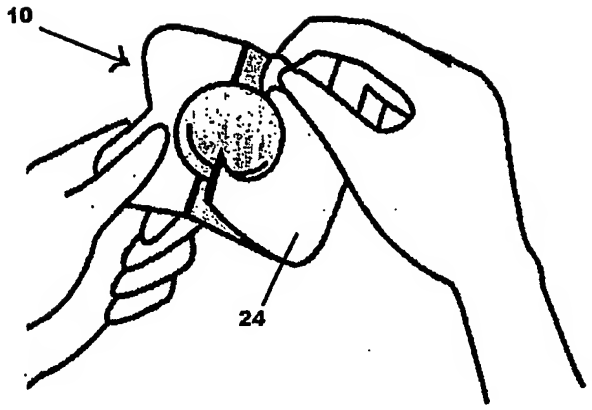


FIG. 3

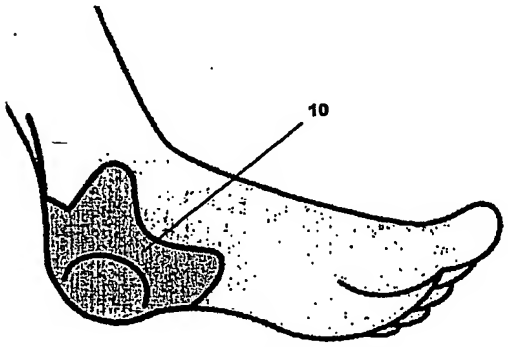


FIG. 4